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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,524

06/26/2003

Tenny Chang

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03/18/2009

CARDICA, INC.

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/607,524	Applicant(s) CHANG ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 31-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 41-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In view of the appeal brief filed on 03/11/2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/T.E.M/

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 41-42 and 45-53 are rejected under 35 U.S.C. 102(b) as being anticipated by **Stefanchik** (U.S. Patent No. **6,187,019**).

Claims 41-42, 45-53: Stefanchik discloses a tissue effector **60** comprising an anvil **110** and a staple holder (“rollers”) **70** or **71** movable relative to said anvil that drives staples **161** and **162** against needle guides on the anvil (Figure 17-19 and cols. 7-8), and a transfer clamp **80** connectable to said tissue effector (Figures 8-9) and configured to register a graft vessel relative to a tissue effector (Figures 10-11), said transfer clamp including two arms **84** and **82** (with arm **82** having a flexible or movable extension **200**) movable relative to one another (Figures 24-25; col. 6, lines 4-6; col. 11, lines 9-39), wherein each said arm includes a substantially planar surface with an edge, wherein the length of each said edge is related to the anastomosis length and wherein said surfaces are substantially opposed to one another (see Figure 17, arms **84** and **82** have flat surfaces at the ends of their C-shape that oppose one another). Since arm **84**, which engages the graft vessel, may also have a flexible extension (col. 11, lines 20-21), Stefanchik discloses a graft manipulator movable relative to said transfer clamp. The flexible extensions may be considered poke-through tips or spikes connected to said

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transfer clamp. The transfer clamp is considered to be “independent” of said tissue effector during actuation thereof since it is capable of being separately actuatable.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 8-11, 13-17, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al., hereinafter “**Gifford**” (U.S. Patent No. **5,695,504**).

Claims 1-4, 8-11, 13-17: Gifford discloses an anastomosis tool **101**, **102** configured to connect the graft vessel and the target vessel upon actuation (wherein “actuation” is considered to be the complete process of bringing the graft and target vessels together), and a transfer clamp **154** including two movable arms with jaws that grasp the graft vessel, said transfer clamp configured to be attached to said anastomosis tool to place the graft vessel on said anastomosis tool and to be detached from said anastomosis tool during actuation, wherein at least one said arm comprises at least one element having an edge, wherein the length of said edge is related to the anastomosis length (Figures 7A-7C; col. 20, lines 27-59). The jaws have gripping surfaces, wherein “gripping surface” is taken to mean a surface that can grip onto tissue. The transfer clamp engages and locks to the anastomosis tool between stop **158** and flange **159**. There is an extension arm **157** or **155** fixed to the transfer clamp.

Gifford does not expressly disclose that both the arms of the transfer clamp are both relative to one another (just one relative to one apparent fixed arm in 7B) or being biased to a closed position, however, it would have been obvious to one of ordinary skill in the art to have both arms movable relative to one another in order to accommodate different-sized graft vessels and to biased to a closed position to ensure a secure gripping engagement of tissue.

Claims 28-30: Gifford discloses that a graft manipulator, such as an endoscopic forceps or nerve hook may be used for grasping the graft vessel and drawing it through the graft insertion tool (col. 18, lines 42-45). It is not expressly disclosed that the manipulator has arms that are biased apart from one another or have prongs, but it would have been obvious to one of ordinary skill in the art to have these features to accommodate different-sized graft vessels and to effectively be secured to the tissue.

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford** (U.S. Patent No. **5,695,504**) in view of **Vargas** (U.S. Pub. No. **2002/0095166**).

Claims 5-7: Gifford discloses the claimed device, except for a cutting block movable and rotatable relative to the corresponding arms.

Vargas '166 teaches a cutting block **206a'-2** movable and rotatable relative to the corresponding arm **206a'** that prevents further cutting of the incision (Figure 10A and page 4, paragraph 56). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotatable cutting block relative to the corresponding

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arm, as taught by Vargas '166 to Gifford in order to prevent further cutting of the incision.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford** (U.S. Patent No. **5,695,504**) in view of **Tartaglia** (U.S. Patent No. **4,318,313**).

Claim 12: Gifford discloses the claimed device, including compression of the arms moving the arms from said closed position to an open position, except for finger pads being coupled to said arms, wherein compression of said finger pads move said arms from said closed position to said open position. It is noted that the finger pads themselves are not the cause of moving the arms from a closed position to an open position, but rather they are coupled to the arms that are compressed, moving the arms from a closed position to an open position.

Tartaglia teaches finger pads **20** and **20'** being coupled to arms **10** and **10'** which provide the user a larger surface area onto which they may place their fingers to prevent slippage, as well as ergonomic benefits (Figure 1 and col. 2, lines 4-8). It would have been obvious to one of ordinary skill in the art to provide finger pads coupled to the arms, as taught by Tartaglia, to Gifford in order to provide the user with ergonomic benefits in using the device.

8. Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford** (U.S. Patent No. **5,695,504**) in view of **Person** (U.S. Patent No. **6,200,263**).

Claims 23-27: Gifford discloses the claimed device, except for a retractor mount connectable to the extension arm, a holder being movable and rotatable relative to a remainder of the retractor mount, being connectable to said extension arm via said holder, and being configured to engage said anastomosis tool.

Person teaches a retractor mount **10** adapted to be connectable to an extension arm, a holder **30** being movable and rotatable relative to a remainder of the retractor mount, being adapted to be connectable to an extension arm via said holder, and being configured to engage an anastomosis tool (Figure 3 and col. 2, lines 29-46). Person teaches that a retractor mount with a holder provides greater versatility, is less invasive, and facilitates selective position adjustment of instruments relative to the retractor mount (col. 2, lines 2-5 and 14-18). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotatable holder connected to a retractor mount, as taught by Person, to Gifford, in order to provide greater versatility, to be less invasive, and to facilitate selective position adjustment of instruments.

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9. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik** (U.S. Patent No. **6,187,019**) in view of **Vargas** (U.S. Pub. No. **2002/0095166**).

Claims 5-7: Stefanchik discloses the claimed device, except for one of the arms having a cutting block movable and rotatable relative to the corresponding arms.

Vargas teaches a cutting block **206a'-2** movable and rotatable relative to the corresponding arm **206a'** that prevents further cutting of the incision (Figure 10A and page 4, paragraph 56). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotatable cutting block relative to the corresponding arm, as taught by Vargas, to Stefanchik in order to prevent further cutting of the incision.

Response to Arguments

10. Applicant's arguments with respect to claims 1-30 and 41-53 have been considered but are moot in view of the new ground(s) of rejection.

Upon further consideration, the Examiner has determined tha Stefanchik '019 anticipates the claims under 35 U.S.C. 102(b) instead rendering them obvious under 35 U.S.C. 103(a) by referring to another embodiment not previously mentioned disclosing both the transfer clamp arms being movable, instead of just one, by virtue of the arms having flexible extensions (Figures 24-25; col. 11, lines 9-39). Looking closer at the anastomosis tool, there is also an anvil **110** and a staple holder ("rollers") **70** or **71** movable relative to said anvil that drives staples **161** and **162** against needle guides on the anvil (Figure 17-19 and cols. 7-8). Lastly, the transfer clamp is considered to be

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“independent” of said tissue effector during actuation thereof in the sense that it is capable of being separately actuatable or movable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734